U.S. DEPARTMENT OF AGRICULTURE
AMS
AGRICULTURAL MARKETING SERVICE

APPROVED

USDA FOOD

TECHNICAL

REQUIREMENTS

SCHEDULE – GB - 2010

FOR USDA PURCHASES OF

GROUND BEEF ITEMS, FROZEN

Effective: July 2010

UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL MARKETING SERVICE

LIVESTOCK AND SEED PROGRAM

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I. SCOPE

This Technical Requirements Schedule (TRS)–GB–2010 is for use by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program to procure frozen ground beef products.

II. APPLICABLE DOCUMENTS

The following documents are incorporated as part of this USDA, TRS-GB-2010:

- Meat Grading and Certification (MGC) Branch Instruction Manual.
- Audit Review and Compliance (ARC) Branch Procedures, Series 1000.
- Food Safety and Inspection Service (FSIS) Directive 10,010.1 Revision 3.

III. CHECKLIST OF REQUIREMENTS

A. ITEMS

The contractor's technical proposal will declare which items will be offered to USDA. Bulk or patties to be specified within USDA procurement documents.

1. Bulk - Product Code

Ground Beef (10-pound bulk packaged)	A608
Ground Beef-Irradiated (10-pound bulk packaged)	A579
Ground Beef, 1-pound packages	A609
Coarse Ground Beef	A594

2. Patties -

Ground Beef Patties	A626
Ground Beef Patties-Irradiated	A578
Beef Patties with Soy Protein Product	A616
Ground Beef Patties, Not to Exceed (NTE) 10% Fat	A627
Ground Lean Beef Patties	A580

B. MATERIAL

The contractor's technical proposal must describe a process plan with a documented quality control program that includes procedures, records, forms, etc., that demonstrate conformance with the following Checklist of Requirements. The Contracting Officer may request changes to the technical proposal at any time.

1. Domestic Origin and Harvest Requirements
   a) Quality Control Program - The harvester's quality control program must be documented in each contractor's technical proposal and have received a satisfactory onsite capability assessment by the ARC Branch.
   b) Boneless beef shall be derived from cattle harvested at facilities that comply with the following origin and harvest requirements.
      (1) Domestic Origin - All beef will originate from U.S. produced livestock as defined in Supplement LS-200, as amended.
      (2) Humane Handling – All cattle shall be humanely handled in accordance with all applicable FSIS regulations, directives, notices, and AMS requirements.
      (3) Spinal Cord Removal – All spinal cord tissue shall be removed during the harvesting process.

(4) Pathogen Intervention Steps – The harvest process must include at least two pathogen intervention steps. One of the intervention steps must be a critical control point (CCP) in their FSIS recognized harvest process Hazard Analysis Critical Control Point (HACCP) plan and the CCP intervention(s) must be scientifically validated to achieve a three log reduction of enteric pathogens.

(5) Carcass Testing - Routinely test carcasses for *Shiga-toxigenic Escherichia coli O157* (including *O157:H7* and *O157*:Non-Motile (NM); herein referred to as *E. coli O157:H7*) at CCP to verify effectiveness of interventions.

2. Boneless Beef Requirements

a) Quality Control Program - The boneless beef supplier's quality control program must be documented within each contractor's technical proposal and have received a satisfactory onsite capability assessment by the ARC Branch prior to supplying materials for the program. Additionally, each plant is subjected to verification audits conducted by the ARC Branch during production activities that demonstrate their adherence to the documented program.

b) Traceability – Boneless beef shall be traceable to sources that comply with the above domestic origin and harvest requirements.

c) Boneless beef commonly referred to by the industry as XF trimmings (e.g., Beef Fat with Visible Lean) is not allowed as a standalone raw material source for grinding.

d) Meat Recovery Systems

(1) Mechanical Separation - Boneless beef that is mechanically separated from bone with automatic deboning systems, advanced lean (meat) recovery (AMR) systems or powered knives, will not be allowed.

(2) Lean Finely Textured Beef (LFTB) – may be used as a raw material in fine and coarse ground beef products provided a scientifically validated intervention is applied during the LFTB manufacturing process that reduces enteric pathogens by at least a three log basis. When LFTB is used, the following criteria must be met:

(a) Red Color – The producer of LFTB shall assure that the product has a discernible redness in color. The LFTB shall maintain the same redness in color until time of processing to minimize the effect of the color to the finished ground beef.

(b) Fat Content - Does not exceed 10 percent fat.

e) Handling - All boneless beef must be maintained in excellent condition. The contractor's technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the boneless beef

(1) Except for boneless beef destined for Ground Beef Products to be irradiated, frozen boneless beef may be used provided it is ground into the final product within 60 days from the date of pack. Boneless beef destined for irradiated ground beef shall never be frozen before grinding and shall be ground within five (5) days from harvest.

(2) The contractor shall document all procedures for handling of LFTB and must use it within 60 days of the date of production.

f) Objectionable Materials – The following objectionable materials shall be excluded:

(1) Major lymph glands (*prefemoral, popliteal,* and *prescapular*), thymus gland, and the *sciatic* (*ischiatic*) nerve (lies medial to the outside round). All bone, cartilage, and the following heavy connective tissues:

(a) White fibrous – Shoulder tendon, elbow tendon, silver skin (from the outside round), *sacrociatic* ligament, opaque *periosteum*, *serous* membrane (*peritoneum*), tendinous ends of shanks, *gracilis* membrane, *patellar ligament* (associated with the stifle joint), and *achilles* tendon.

(b) Yellow elastin – Back strap and *abdominal tunic*.

g) Lot – A lot shall consist of a single combo sized bin of approximately 2,000 pounds of boneless beef (including LFTB) produced between "cleanup to cleanup" (see APPENDIX D) and that is from a single harvester or from a single processor.

h) Microbial Testing – All lots of fresh chilled boneless beef, including finely textured beef, must be tested for all microbes listed in APPENDIX B. All samples will be sent to the AMS designated laboratory (ADL).

(1) Sample Preparation and Handling - The ADL will be responsible for supplying sampling procedures for sample selection, preparation, and submission. The sampling procedure shall include sampling plans including sample size (weight, packaging and handling instructions, including handling of reserve samples, and procedures for submitting samples to the laboratory). The procedure for submitting samples shall include a laboratory form to be filled out by the supplier containing sample tracking information including, but not limited to, company name, contact person, contact information, lot number, pounds of product represented by sample, and production date. The laboratory shall require suppliers to submit this form as an official record with each sample. The laboratory will also be responsible for supplying shipping supplies (including sampling bags and shipping materials), to each supplier. Suppliers' technical proposal will include and describe sample collection and preparation procedures provided by the ADL.

(2) Sample Selection

(a) For Beef Manufacturing Trimmings – The composite sample will be selected as described within FSIS Directive 10,010.1 Revision 3 (N-60 Sections 8, 9 and NOTE).

(b) LFTB - Randomly selected.

(c) The composite sample (boneless beef or LFTB) shall weigh 350 - 385 grams.

(d) When boneless beef has been exposed to any anti-microbial treatment, no sample units shall be selected for at least 15 minutes after such treatment.

(3) Testing and Results

(a) The microbiological testing for all microbes will be in accordance with the applicable FSIS test methods.

(b) Notification for presence of pathogens and exceeding critical limit criteria - When presence of *E. coli O157:H7* or *Salmonella* is presumptive positive or confirmed positive or any critical limit is exceeded for indicator microbes:

(i) The ADL will immediately notify FSIS and AMS.

(ii) When presence of pathogens is positive, FSIS and AMS will be notified by the boneless beef supplier of the final disposition of the product.

(iii) When the critical limit is exceeded for indicator organisms, the boneless beef supplier will notify AMS of the final disposition of the affected lot.

(iv) Confirmed pathogen - The boneless beef supplier shall conduct a cause and effect analysis to determine the appropriate corrective action necessary to eliminate the probable cause.

(c) The ADL will record results of all microbial analysis in a format that can be easily captured and analyzed.

(d) The ADL will record results on spreadsheets and plot the results on control charts and histograms for each Microbial Testing performed on each approximately 2,000 pound lot (as illustrated in APPENDIX A and further defined in APPENDIX D).

(e) Any lot that tests positive for *E. coli O157:H7 or Salmonella,* or exceeds the critical limit criteria of APPENDIX B cannot be used to produce ground beef or any other product purchased by USDA.

(4) Statistical Process Capability – The statistical process capability of a boneless beef supplier to comply with microbial requirements will be based on the assessment of control charts and histograms derived from the individual combo test results representing one (1) 2,000 pound combo lot randomly selected by the ADL from every five (5) consecutive individual 2,000 pound combo lots produced each production day. In the event that a production day concludes with less than five (5) consecutive individual 2,000 pound combo lots, a randomly selected test result will be utilized from one of the remaining lots. The control charts, histograms, and spreadsheets will be maintained so that process capability assessment on the twenty (20) lots can be determined as described within APPENDIX B. Test results involving all boneless beef offered for testing for AMS ground beef purchase programs will be monitored by AMS, the contractor, and the boneless beef supplier to determine individual lot acceptance and/or capability of their process according to APPENDIX B. The boneless beef supplier will notify the contractor and Contracting Officer and, in turn, the Contracting Officer will direct the ADL regarding charting and computation needs due to any change in status.

(5) Contractor's Responsibility - The contractor will require their boneless beef supplier(s) to provide results and process capability status (as applicable) involving each lot of boneless beef to be processed into ground beef for USDA. Process Capability Status for individual lots shall be provided to the MGC Branch agent upon request. In the event a boneless beef supplier has been deemed ineligible, and wants to continue in the program, the ineligible boneless beef supplier must first provide the contractor and AMS their plan to implement corrective actions. Once the plan is agreed to by the contractor and AMS, then the boneless beef supplier must receive a satisfactory onsite assessment audit from AMS. Upon notification by the Contracting Officer that the plan has adequately addressed the issues that resulted in the ineligible status determination the boneless beef supplier may renter the program under conditional status.

3. Ground Beef Requirements
   a) Quality Control Program - The ground beef quality control program must be documented within the contractor's technical proposal and have received a satisfactory onsite capability assessment by the ARC Branch.
   b) Traceability – All ground beef must be traceable to the production lots and associated microbial test results for each lot of boneless beef and LFTB used in the production of that lot.
   c) Handling - The contractor's technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the ground beef. Except for ground beef, 1-pound packages, all other ground beef items shall be delivered within 60 days from date of pack. Ground Beef 1-pound packages shall be delivered within 30 days from date of pack.
   d) Lot - For the purpose of microbiological testing, a lot is defined as the amount of finished ground beef product, for each product code, produced between "cleanup to cleanup" (see APPENDIX D) which must be further divided into 1 hour sub-lots (not to exceed 10,000 pounds).
   e) Microbiological Testing – All lots of ground beef will be tested for all microbes listed in APPENDIX B after final grinding and before freezing, except for ground beef products that are irradiated. The irradiated products will be tested for *Salmonella* and *E. coli O157:H7* after the irradiation process, and the other microbes listed in APPENDIX B prior to irradiation. All samples will be sent to the ADL.
      (1) Sample Preparation and Handling- The ADL will be responsible for supplying sampling procedures for sample selection, preparation, and submission. The sampling procedure shall include sampling plans including sample size (weight) in accordance with the applicable TRS, packaging and handling instructions, including handling of reserve samples, and procedures for submitting samples to the laboratory. The procedure for submitting samples shall include a laboratory form to be filled out by the supplier containing sample tracking information including, but not limited to, company name, contact person, contact information, lot number, pounds of product represented by sample, and production date. The laboratory shall require suppliers to submit this form as an official record with each sample. The laboratory will also be responsible for supplying shipping supplies (including sampling bags and shipping materials) to each supplier. Contractor's technical proposal will include and describe sample collection and preparation procedures provided by the ADL.
      (2) Sample Selection – Production processes of ground beef will be subject to the following sampling strategies:
         (a) Whole Lot Microbial Testing - From each lot ("cleanup to cleanup"), a composite and reserve sample will be prepared from eight randomly selected sample units (of approximately equal size) of finished ground beef. The sample units shall be blended. From the mixture, a single sample weighing 350-385 grams shall be submitted to the ADL for analysis. A reserve sample of the same weight shall be drawn and held for testing in case the Contracting Officer deems it necessary. The Whole Lot Microbial Testing ("cleanup to cleanup") will be utilized for assessment of control charts and histograms.

(b) Sub-lot Microbial Testing – For every 1 hour of production, a composite and reserve sample of 350-385 grams will be prepared from individual sample units (approximately 88-92 grams) of finished ground beef, selected from each 15 minutes of production. The sample units shall be blended to produce a composite sample that represents each 1 hour sub-lot. This sample shall be submitted to the ADL for analysis. The reserve sample will held for testing in case the Contracting Officer deems it necessary. The contractor will describe, in their technical proposal, the approach taken for documenting the amount of ground beef produced for each 1 hour sub-lot, as well as, the method to be used to maintain the identity and traceability of each 1 hour sub-lot. No more than 10,000 pounds shall be produced during each one hour sub-lot. In the event that more than 10,000 pounds is produced in an hour, the contractor shall adjust the production sub-lot to reflect the 15 minute time increment adjustment (e.g., 45 minutes) that represents 10,000 pounds or less. Additionally, the contractor shall adjust the sample unit size criteria to yield a 350-385 gram sample that reflects the applicable number of 15 minute interval sample units.

(3) Testing and Results - The sample from each Sub-lot and composited Whole Lot sample will be analyzed by the ADL for all microbes listed in APPENDIX B.

(a) The microbiological testing for all microbes will be in accordance with the applicable FSIS test methods.

(b) Any Whole Lot sample that tests positive for *E. coli O157:H7* or *Salmonella* or any critical limit criteria noted in APPENDIX B that is exceeded will result in the complete lot ("clean up to clean up") being ineligible for this program or any other USDA purchase program.

(c) Any Sub-lot that tests positive for E. coli O157:H7 or *Salmonella* or any critical limit criteria noted in APPENDIX B that is exceeded will result in that Sub-lot and adjoining Sub-lots (one preceding and one following within "clean up to clean up") being ineligible for this program or any other USDA purchase program. Other Sub-lots produced within that Whole Lot unit will be deemed ineligible for this program unless the contractor can demonstrate a scientific or other data-supported basis for defining the sub-lot(s) relative to test results and why ground beef produced from same source material that resulted in the ineligible determination should not be considered affected by the test results.

(d) Notification for presence of pathogens or when critical limit is exceeded – When presence of *E. coli O157:H7* or *Salmonella* is presumptive positive or confirmed positive; any critical limit is exceeded for indicator microbes, or when both the initial and reserve sample of *Staphylococcus aureus* exceeds the upper specification limit of APPENDIX B:

(i) The ADL will immediately notify FSIS and AMS.

(ii) When presence of pathogens is positive FSIS and AMS will be notified by the contractor of the final disposition of the product.

(iii) When the critical limit is exceeded for indicator organisms, or when both the initial and reserve sample of *Staphylococcus aureus* exceeds the upper specification limit of APPENDIX B, the supplier will notify AMS of the final disposition of the affected lot.

(iv) Confirmed Pathogen - The contractor shall conduct a cause and effect analysis to determine the appropriate corrective action necessary to eliminate the probable cause.

(v) The ground beef associated with the positive pathogen test results or critical limit exceeded results will be ineligible for any USDA purchase program.

(e) The ADL will record results on spreadsheets and plot the results on control charts and histograms for each test performed on each Sub-lot and Whole Lot (as illustrated in APPENDIX A and further defined in APPENDIX D).

(f) Statistical Process Control Evaluation

(i) Sub-lot test results will not be used for control charts and histogram evaluation.

(ii) The ADL will record and plot the results on control charts and histograms for each Whole Lot microbial test performed on the composite sample obtained from the eight randomly selected individual samples (as illustrated in APPENDIX A and further defined in APPENDIX D). The control charts and histograms will be maintained so that process capability may be determined according to the requirements within APPENDIX B. Test results will be monitored by the contractor and AMS to determine acceptability of the process according to APPENDIX B. The contractor will advise the AMS agent and the ADL of their process capability status for each lot. The contractor will notify the Contracting Officer and, in turn, the Contracting Officer will direct the ADL regarding charting and computation needs due to any change in status. Ineligible contractors may petition AMS to reenter the program under conditional status provided corrective actions have been implemented, proven effective, and a satisfactory onsite assessment audit by AMS has been received.

g) Irradiated Ground Beef - When specified by the purchaser, ground beef products to be irradiated shall comply with the additional requirements specified in APPENDIX C.

h) Beef Patties with Soy Protein Product (SPP) - The SPP will be hydrated to yield no less than 18% protein (as is basis).

[(Percent Protein of SPP on “as-is” Basis / 18) – 1] = x

x = maximum pounds of water to be added to each pound of dry SPP.

(1) Texture - The physical characteristics of SPP, in the dry form, must be either granular or textured.

(2) Type and Combination Rate - The types of soy that may be used and combination rates shall be as set forth in Table 1.

Table 1

Types of Soy (% Protein "As is Basis")	**Maximum % of Hydrated SPP in each batch of Combined Finished Product**
Granular Concentrate (65%)	20.0
Flaked Textured Concentrate (65%)	25.0
Textured Isolate (85%)	25.0

NOTE: SPP (of any texture) that has been hydrated by the SPP manufacturer may be used provided that: The product is frozen and the protein content (as is basis) of the hydrated SPP is stated on the manufacturer's label.

i) Ground Beef Patties, NTE 10 percent Fat – The patties shall not have any non-meat ingredients added.

j) Ground Lean Beef Patties – Non-meat components may be used to enhance the palatability of the patties comprising no more than 15 percent of the raw formula. The contractor's technical proposal must list all ingredients (i.e., water, processing aids, binders, seasonings, etc.) within their formula.

C. PROCESSING

The contractor's technical proposal and process shall assure compliance with the following requirements:

1. Grinding and Blending -
   a) Ground Beef - Boneless beef shall be ground twice, with the final grind passing through a 1/8 inch grinding plate. Blending after final grinding is allowed only to the extent that it doesn't affect the appearance of the finished ground beef.
   b) Coarse Ground Beef - Boneless beef shall pass at least once through a grinding plate that is no smaller than 3/4 inch or no larger than a 1.0 inch. Blending after final grinding is allowed only to the extent that it doesn't affect the appearance of the finished ground beef.
   c) Fat Break-Outs - The grinding, blending, and packaging process shall be conducted in a manner that precludes large fat "break outs" (solid chunks of fat greater than 1.0 cubic inch) or objectionable fat "smears" in the finished product.
   d) LFTB – LFTB will not exceed 15 percent by weight of each batch of combined finished product. For coarse ground beef, LFTB will not exceed 10 percent by weight of each batch of combined finished product.

2. Bone Collector/Extruder Systems - Except for Coarse Ground Beef, a bone collector/extruder system must be in operation to remove remaining bone, cartilage, and heavy connective tissue during the final grind. For those collector/extruder systems that have a secondary lean recovery system, the product from the secondary recovery system shall be allowed provided it does not exceed more than 2.0 percent of finished product weight (on a batch weight basis).

3. Shape and Waffling of Patties - Ground beef patties must be round or oval in shape and waffled or scored on both sides.
4. Metal Detection - All product shall be free of metal contaminates. Detection of stainless steel, ferrous, and non-ferrous (e.g., lead, copper, and aluminum) metals is required. The contractor's technical proposal must identify and describe the equipment, location, detection procedure, sensitivity levels, frequency of equipment validation, and corrective action procedures.
5. Equipment – All equipment used to produce ground beef products for USDA shall be maintained and routinely checked for optimal performance.

D. STATE OF REFRIGERATION

1. Bulk Packaged Ground Beef Items - Shall be frozen to 0^{o}F within 72 hours after completion of the final grinding of the involved lot.
2. Patties - will be individually quick frozen (IQF) to 10^{o}F or below prior to packaging and then frozen to 0^{o}F or lower within 24 hours after completion of packaging and packing of the lot. Patties will not stick together after they are packaged and packed.
3. All USDA ground beef products will be stored, shipped, and delivered at temperatures that do not exceed 0^{o}F.

E. FAT LIMITATIONS

The contractors will establish a target average of 15 percent fat for all ground beef products except for the ground beef patties NTE 10 percent fat and ground lean beef patties. The upper and lower specifications limits will be 18 and 12 percent fat respectively. The target fat content will be declared on the shipping container label and the nutrition facts panel. For ground beef patties NTE 10 percent fat, the upper specification limit will be 10 percent and the contractor will declare their target. For ground lean beef patties, the average fat target shall be 5 percent with upper and lower specification limits being 6 and 4 percent fat respectively. Separate Statistical Process Control (SPC) assessments will be conducted on ground beef products with a targeted average of 15 percent fat, the NTE 10 percent fat patties, and the ground lean beef patties.

1. Contractor Process Assessment - The contractor shall declare the production lot size, laboratory, test method, and SPC charting method in their technical proposal.
   a) Sampling and testing - The contractor will randomly select four individual sample units (selected after initial grinding or blending) to be analyzed for fat content from each production lot destined for USDA. The sample unit size will be determined by the testing method used by the contractor's laboratory.
   b) Recording results - The contractor will record and plot the results on variable data control charts and histograms (as illustrated in APPENDIX A and further defined in APPENDIX D). Control charts must have statistically derived upper and lower control limits (+/- 3 standard deviations from the mean). Control charts will be used to determine if the process is in statistical control. Histograms will be used to determine process capability. Under contractor process assessment, no production lots shall be allowed delivery to USDA with average test results that are outside the upper or lower specification limits.

c) Process Capability Assessment - Twenty (20) consecutive production lot results (that include the last production lot) will be plotted on histograms for capability assessment by the contractor and the AMS agent. The processor's capability (Cpk/CPU) shall be one or higher.

2. AMS Process Assessment – For the first 20 production lots, the AMS agent will direct the contractor to randomly select samples, each consisting of four sample units. For finely ground beef, each sample unit shall not exceed 2 pounds. For coarse ground beef, each sample unit shall not exceed 10 pounds. Each sample unit shall be independent from those samples selected for contractor process assessment and sent to the ADL for fat analysis. The ADL will be responsible for supplying sampling protocol, all sample handling materials, and sampling methods (including sample unit size to be submitted to the ADL, preparation, handling of reserve samples, etc.) for sample preparation and submission. The ADL will plot the results on x-bar/ range and histograms charts (see APPENDIX A) and submit them to the contractor and AMS for comparison to the contractor's process assessment. After 20 consecutive results, the contractor shall notify the AMS Contracting Officer immediately and declare what immediate corrective and preventative actions will be taken when:
   a) The ADL calculated process average fat results (mean) varies more than 1 percent from the contractor's calculated process average results, or
   b) The calculated process capability (Cpk/Cpu) is less than one for results from either the contractor's designated laboratory or the ADL.

   The Contracting Officer reserves the right to deem a contractor as unreliable for consideration on future contract awards when corrective or preventative actions are not adequate or effective. If the Contracting Officer determines that such actions are adequate, then the Contracting Officer will request sampling and testing of an additional 20 consecutive lots.
3. Continuous AMS Assessment – If AMS process assessment is satisfactory, the AMS agent will direct the contractor when to randomly select samples (each consisting of four sample units) from a production lot. No more than two production lot samples are sent to the ADL on a weekly basis. The ADL will continually plot 20 consecutive results (always including the last recorded result as defined within APPENDIX D) on x-bar and range control charts and histograms (see APPENDIX A) and submit them to the contractor and AMS. The ADL's histograms will continually be compared to the Contractor's histograms as each Contractor's test result is recorded to conduct the AMS Process Assessment as described above (using 20 consecutive results).

F. PATTY WEIGHT, THICKNESS, SHAPE, AND COLOR

The contractor's technical proposal and process will assure, using SPC tools, that the following requirements are met:

1. Patty Weight
   a) Product Codes A626, A616, 578, 627 - Target weight will be 3.0 ounces. Acceptable weight tolerance range will be 2.9 to 3.1 ounces.
   b) Product Code A580 - Target weight will be 3.1 ounces. Acceptable weight tolerance range will be 3.0 to 3.2 ounces.

2. Patty Thickness – 5/16 inch (+/- 1/16).
3. Shape - Patties shall be round or oval in shape and waffled or scored on both sides.
4. Color – Color of patties shall be monitored for normal appearance and color. When cooked to an internal temperature of 160^{o}F by the end user, patties with internal or external pink appearance will not be allowed.

G. PREPARATION FOR DELIVERY

The contractor's technical proposal and process will assure that all packaging, packing, closure, marking, and palletization comply with the National Motor Freight Regulations and FSIS regulations and the requirements listed below. The contractor also must have procedures for verifying the net weight of shipping containers.

1. Packaging and Packing
   a) All immediate containers (casings or packages) shall function as a tamper evidence indicator to provide added assure of product integrity through the method of sealing or closure.
   b) Fine Ground Beef (Product Code A608) – Fine ground beef must be vacuum packaged or packaged in casings and sealed. All packages will weigh 10 pounds. The casings or packages shall be closed by metal clips or by a heat-sealing method. Four (4) packages will be placed into each shipping container.
   c) Fine Ground Beef (Product Code A609) – Fine ground beef must be vacuum packaged or packaged in casings and sealed. All packages will weigh 1 pound. Forty (40) packages will be placed into each shipping container.
   d) Fine Ground Beef-Irradiated (Product Code A579) – Fine ground beef must be vacuum packaged in a thermo formed plastic container. Each package shall weigh 10 pounds. The package shall be rectangular in shape and shall be made from materials that have been approved by FDA for irradiation application. Packages shall be packed into shipping containers with net weights of 40 pounds. The depth, width, and length of the containers shall be considered depending on the type of ionizing radiation used.
   e) Coarse Ground Beef (Product Code A594) - Coarse ground beef must be bulk packaged (with no packaging materials) directly into leak-proof shipping containers with fiberboard that is wax impregnated, has a moisture barrier coating, or have plastic laminated interior panels.
   f) Patties (Product Codes A616, A626, A627, A580) - Patties must be placed into immediate containers following either of the following methods. Separation material between patties is not required provided the IQF patties do not stick together at the time of shipment.
      (1) Flexible Containers - Either four 10-pound, five 8-pound, or eight 5-pound flexible (plastic) vacuum packaged or sealed containers will be placed into each shipping container. Hand twisting or hand tying is not acceptable.
      (2) Fiberboard Containers – When fiberboard is used for immediate containers, either four 10-pound or two 20-pound fiberboard containers will be placed into each shipping container. Patties may either be:
         (a) vacuum packaged or within sealed flexible containers (hand twisting or hand tying is not acceptable) when placed into the fiberboard immediate container or,

(b) placed into the fiberboard immediate container that is lined with a plastic bag to completely cover the product. For this option, fiberboard immediate containers will then have to be sealed with tape or glue.

g) Ground Beef Patties-Irradiated - (Product Code A578) – Patties must be packaged into sealed flexible (plastic) immediate containers. They may weigh either 20 pounds or 10 pounds. Packaging materials shall be approved by FDA for irradiation application. Separation material between patties is not required provided the IQF patties do not stick together at the time of shipment. Packages will be packed into shipping containers with net weights of 40 pounds. Consideration of the depth, width, and length of the containers shall be considered depending on the type of ionizing radiation is used.

h) Style and Size of Shipping Containers - Only one style and size of immediate and shipping container may be used in any one delivery unit.

2. Shipping Container Net Weight – Using SPC tools, the contractor shall assure the following net weights.

a) Ground Beef (1/8 inch fine ground bulk and patties) - will be packed to a net weight of 40 pounds.

b) Coarse Ground Beef - will be packed to a net weight of 60 pounds.

3. Closure

Shipping containers will be closed by strapping, taping or gluing. When strapping is used, the initial closure (usually the bottom of container) shall be secured by the gluing or taping method.

4. Marking of Containers*

Both, immediate and shipping containers, will have a printed code that includes the establishment number and is traceable to the production lot and date. All container markings shall include all information required by FSIS along with the additional information listed below:

a) Ground Beef, 1-pound package labels will have the following information included on commercially labeled packages:

(1) Safe handling instructions.

(2) Nutrition Facts panel (to include fat declaration of 15 grams of fat per 100 gram serving).

(3) The “best if used by” date (180 calendar days from the date of production).

(4) The FSIS establishment number.

(5) A code number that will indicate traceability to production lot and date.

b) Shipping Containers - Commercially marked shipping containers will include the information as follows:

(1) USDA Shield (at least 2 inches high and appearing on the top of the container or on the principle display panel).

(2) Applicable Contract Number.

(3) The product name shall include no additional disclaimers and qualifiers to the name and code listed in Table 2.

(4) Fat Declaration.

(5) Shipping containers containing irradiated ground beef shall bear the required FSIS markings for irradiated products and a "best if used by date" (180 calendar days from date of production).

(6) Nutrition Facts panel (to include fat declaration of 15, NTE 10 or 5 grams of fat per 100 gram serving, as applicable).

(7) Ingredient declaration (including single ingredient products).

Table 2

Product Name that shall appear on the label	Product Code
Ground Beef 1/	A608
Ground Beef, 1 pound packages	A609
Ground Beef – Irradiated 1/	A579
Coarse Ground Beef	A594
Ground Beef Patties 1/	A626
Beef Patties with SPP 1/ 2/	A616
Ground Beef Patties-Irradiated 1/	A578
Ground Beef Patties NTE 10 percent fat 1/	A627
Ground Lean Beef Patties 1/	A580

1/Shall include the statement "For Institutional Use Only" on the principle display panel.
2/The ingredient statement must include the identification of the added hydrated SPP.

*All labeling shall be illustrated in the Contractor's technical proposal.

5. Palletized Unit Loads – All products shall be stacked on new or well-maintained pallets and palletized with shrink wrap plastic.
6. Total Net Weights Per Delivery Unit - The delivery units for each of the respective product codes are as follows:

Product Code	Pounds Per Delivery Unit
A608, A609, A579	40,000
A626, A616, A627, A578, A580	38,000
A594	42,000

Note: No tolerances will be allowed.

7. Sealing - All products must be delivered to AMS assigned destinations under seal with tamper proof, tamper resistant, serially numbered, high security seals that meet the American Society for Testing and Materials Standard F 1157-04 as required under this supplement.

H. USDA QUALITY ASSURANCE

1. Warranty and Complaint Resolution -
   a) Warranty – The contractor will guarantee that the product complies with all contractual requirements.
   b) Complaint Resolution – The contractor's technical proposal must provide the steps taken to resolve complaints received on the product (i.e., point of contact, cause and effect analysis, corrective and preventative actions taken, and product replacement).
2. AMS Monitoring and Production Assessment -

   An AMS Meat Grading and Certification Branch agent must be present during the grinding process for all USDA ground beef contracts. The AMS agent will monitor and verify the processing steps, quality assurance activities, and corrective actions to assure that all requirements outlined in the approved technical proposal are complied with. The AMS agent will be conducting the monitoring and production verification in accordance with applicable MGC instructions. Any deviations to contractual requirements will be reported to the Contracting Officer.
3. Control of Non-Conforming Product -

   The contractor must include a plan to assure that non-conforming product (i.e., boneless beef, LFTB, ground beef) is not delivered under USDA contracts. The plan must address 1) control and segregation of non-conforming product, 2) removal of any USDA markings, and 3) disposition of non-conforming product, including vendor notification in writing to the Contracting Officer of final disposition (e.g., diverted to cooked product or destroyed).

4. Checkloading -

   The contractor has the following checkloading options:
   a) Option 1 - At the request of the Contractor, AMS agents (on a fee basis) will checkload the product at the time of shipment and perform the following duties:
      (1) Assure product temperature is at or below 0º F at the time of shipment.
      (2) Conduct a final examination of condition of shipping containers that will be limited to visually scanning (without destructive sampling) the delivery unit for defects which may have occurred during handling and storage (e.g., crushed, torn, dirty, stained, etc.). All defective containers are unacceptable and must be corrected, removed or replaced, as applicable.
      (3) Supervise the loading and sealing of each truck.

(4) Issue a final Acceptance Certificate, thereby allowing the Contractor to immediately submit invoice for payment to USDA. The AMS agent shall set forth on the original certificate the following:

(a) Contract number

(b) Notice-to-Deliver number

(c) Destination

(d) Name of product

(e) Product Code

(f) Production lot number(s) and the date each lot was produced along with the shipping container and immediate container code(s) and the code used that provides traceability to establishment number, production lot and date

(g) Count of shipping containers and total net weight in each production lot

(h) Total net weights per delivery unit

(i) Identity of conveyance (numbers and letters, seals, license, etc.) as applicable

b) Option 2 - If the Contractor chooses to not have an AMS agent perform checkloading at the time of shipment, invoices for payment must be supported by:

(1) a recipient's signature on the bill of lading;

(2) a consignee's receipt evidencing date shipped and received; or

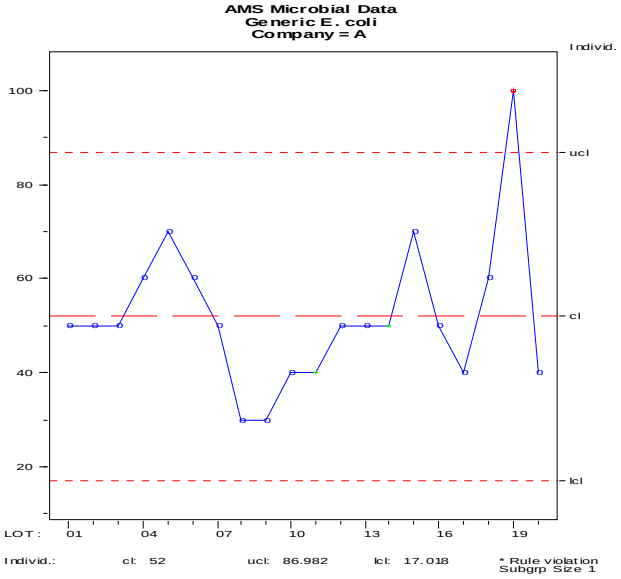
(3) other commercial receipt evidencing delivery of the product.

In all cases, the information contained in the issuance of the final certificate “a through i” in the option 1 section and a statement that: "Product conforms with the TRS-GB-2010" must be included.

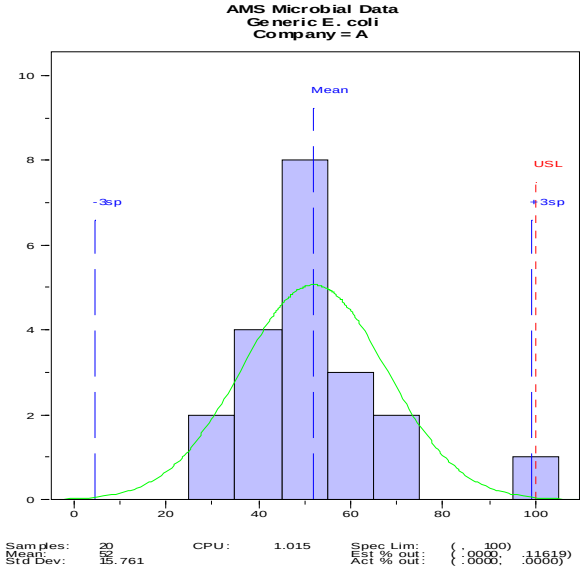
APPENDIX A

Example Statistical Process Control Charts and Histograms

Control Chart



Histogram



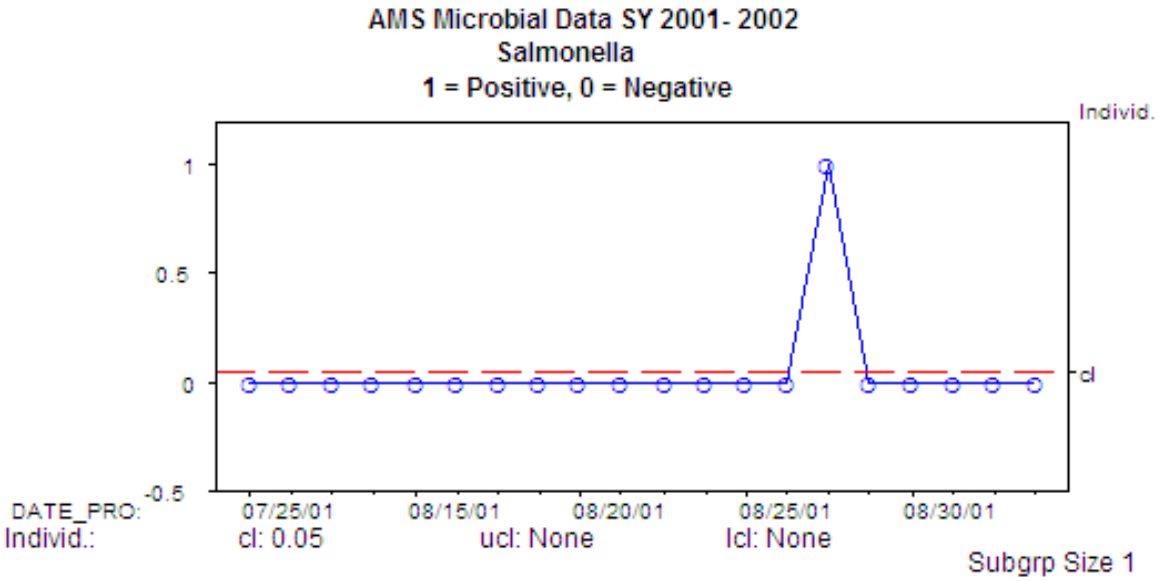
The above control chart and histogram are examples for illustrative purposes.

The control chart will have statistically derived upper control limits (ucl) and lower control limits (lcl) (+/- 3 times the standard deviation of the process average), and the central line (cl) value (process average, mean or x-bar). Since the subgroup size for microbial test is one (1), the calculation for standard deviation will be on individual measures. For data entry purposes, when microbial test results are preceded with < (less than) symbols preceding the values, the value to be entered will be the number minus one (i.e., "<10" will be entered as "9"; "<2500" will be entered as "2499").

The process capability value (Cpk or CPU) is found in the histogram chart (capability report). Since there are no lower specification limits within USDA microbial requirements and fat requirements for ground beef patties NTE 10% fat, the CPU will be used. The Cpk will be used for fat requirements that have an upper and lower specification limit. The applicable upper specification limits (USL) along with the capability limits (+/- 3 times the standard deviation of the individual measures (+/- 3sp)) will be displayed within the histogram. USL for microbial requirements will be found in APPENDIX B. The calculations for process capability are as follows:

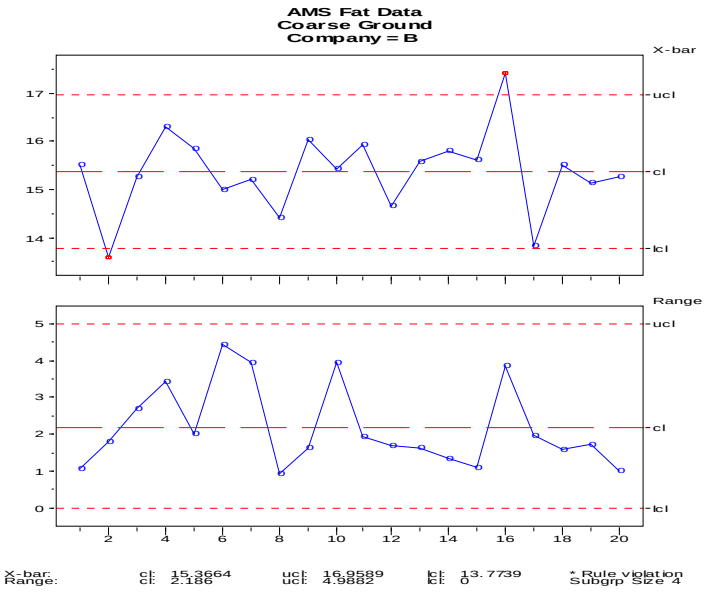
Calculation of process capability (CPU) with an upper specification limit only	**Calculation of process capability (Cpk) with an upper and lower specification limit**
Step 1. The first calculation will determine the Z-value (upper): **Z-value (upper) = (USL – Process Average) / Standard Deviation** Step 2. The Z-value divided by 3 will calculate the CPU: **CPU = Z-value (upper) / 3**	Step 1. The first set of calculations will determine the smaller value of the two Z-values (upper or lower): **Z-value (upper) = (USL – Process Average) / Standard Deviation** **Z-value (lower) = (Process Average – LSL) / Standard Deviation** Step 2. The smaller of the two Z-values (upper or lower) divided by 3 will calculate the Cpk. **CPU = Z-value (smaller value of the upper or lower) / 3**

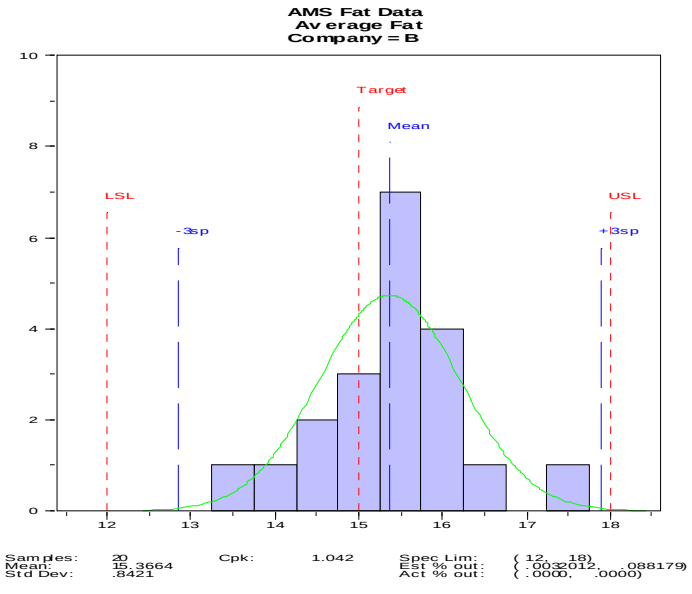
Control Chart



The central line (cl) in the above control chart indicates the incidence of positive *Salmonella* results (5.0%). The results are plotted with the positive results for *Salmonella* and *E. coli O157:H7* as 1 and negative results as 0.

The charts below are illustrative of the x-bar and range control chart and the histogram that shall be used for analysis of fat test results.





APPENDIX B

AMS BONELESS & GROUND BEEF PROCESS REQUIREMENTS FLOW CHART

Quality Control Program – Prior to bidding on ground beef contracts with the USDA, the documented quality control program as described within the technical proposal (raw material suppliers and grinders) must have received a satisfactory onsite capability assessment by the ARC Branch. AMS will audit and monitor the program. The quality control program must specifically address management of microbial data to comply with the AMS Process Requirements Flow Chart and following descriptions.

Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots (which will include the last recorded result as defined within APPENDIX E) of boneless or ground beef destined for USDA contracts for the microbes listed within the table below. When the upper specification limits (USL) are exceeded for *Staphylococcus aureus* (*S. aureus*), a reserve sample shall be submitted to the laboratory for testing. If the results for the reserve sample exceed the upper specification limit for *S. aureus*, the production lot will not be allowed delivery to USDA.

Process Capable? – Flow chart decision step that involves test results for up to 20 consecutive lots (which will include the last recorded result) plotted on control charts and histograms (See APPENDIX A) for evaluation. A process that is not capable shall be declared to the Contracting Officer immediately when results are known and will result in switching from process assessment status to conditional status or switching from conditional status to ineligible status when:

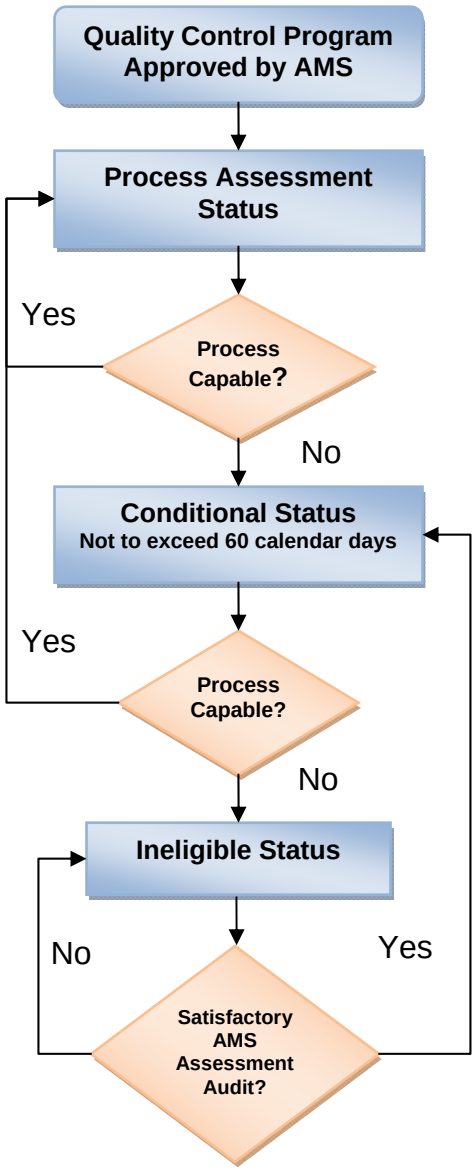
- The CPU values do not meet the levels specified in the table below;
- The CI values do not meet the levels specified in the table below for *Salmonella* or *E. coli O157:H7*;
- Two results exceed any of the critical limits in the table below; * or
- After 2 or more results, the CPU value is negative.*

*Immediate action will be taken prior to completion of 20 lots.

Conditional Status –To regain process assessment status, the boneless beef supplier or contractor must declare to the Contracting Officer that the process is not capable, and then have 20 consecutive results that meet the **'Process Capable?'** criteria within 60 calendar days or in accordance with a production schedule pre-approved by the Contracting Officer. Change in status begins after a cause and effect analysis has been performed and corrective actions have been implemented. The boneless beef supplier or contractor may also declare itself ineligible at any time.

Ineligible Supplier/Contractor – An ineligible Boneless Beef Supplier or Ground Beef Contractor will not be allowed to supply boneless or ground beef products under USDA contracts until corrective actions have been implemented, proven effective, and a satisfactory AMS assessment audit has been completed. Once satisfactorily becoming eligible, subsequent production will be under **Conditional Status.** The AMS Contracting Officer reserves the right to declare a boneless beef supplier or ground beef contractor ineligible at any time.

AMS PROCESS REQUIREMENTS FLOW CHART



AMS MICROBIAL REQUIREMENTS FOR BONELESS & GROUND BEEF			
Microbial Test	**USL**	**Critical Limits**	**CI or CPU Value**
Standard Plate Count	50,000 / gram	100,000 / gram	**CPU ≥ 1**
Total Coliforms	100 / gram	1,000 / gram	**CPU ≥ 1**
E. coli	100 / gram	500 / gram	**CPU ≥ 1**
***Staphylococcus aureus*	500 / gram	N/A	N/A
Salmonella		Positive (+) result / 25 grams	**CI ≤ 0.05**
E. coli O157:H7		Positive (+) result / 325 grams	**CI ≤ 0.05**

** *Staphylococcus aureus* testing will only be conducted on samples from ground beef production lots.

APPENDIX C

REQUIREMENTS FOR GROUND BEEF-IRRADIATED PRODUCTS

Ground Beef-Irradiated products shall be subjected to ionizing radiation from gamma ray, electron beam, or x-ray sources. The following requirements are in addition to all requirements specified within this TRS.

Handling

Products shall be packaged and placed into shipping containers and frozen to 0°F within 72 hours from time of completion of the production lot prior to irradiation. Products must be maintained in a frozen state from the time of leaving the shipping freezer and throughout the irradiation process. After irradiation, the products must be palletized, reloaded, and dispatched to the final destination.

Dosimetry

Ground beef shall be subjected to ionizing radiation to receive a dosage that is no less than 1.35 kilograys (kGy) and no more than 3.00 kGy. Irradiation facilities shall:

- Submit the initial dosimeter data verifying minimum and maximum dosages received within the technical proposal, and
- Maintain and provide confirmation dosimeter data to AMS upon request for each unit of ground beef irradiated.

Microbial Testing

Irradiated Ground Beef Products (patties and bulk) - shall be tested for Standard Plate Count, Total Coliforms, *E. coli*, and *Staphylococcus aureus* after final grinding and before freezing and tested for *Salmonella* and *E. coli O157:H7* after completion of the irradiation process.

APPENDIX D

Glossary of Terms

Cause and Effect Diagrams – A cause and effect analysis is used to identify the cause or source of non-conformities. It categorizes the source as derived from impact on a process presented by Human, Machinery, Material, Methods, Environment, and Measurement (Test). The Cause and Effect Diagram will assist in evaluating a process and assigning the appropriate control point (see Figure 1).

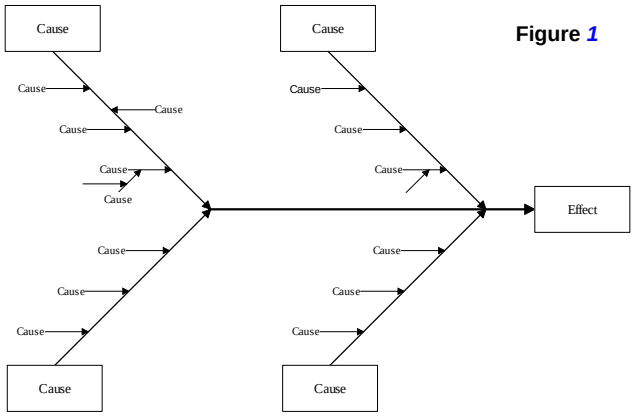


Figure *1*

"Cleanup to cleanup" - Part of a HACCP program that the establishment has in place to support statistically distinguishing one portion of production from another. "Cleanup to cleanup" may be an effective means of preventing cross contamination of one part of production to another with *E. coli O157:H7*. However, "cleanup to cleanup" without other supporting documentation may not be adequate to statistically distinguish one portion of production from another. If a sample analysis yields a positive result, any product produced in the same time frame with the same process or equipment is suspect, unless an intervention occurred that would indicate a change in the status of the process/equipment.

Control Charts – A control chart is a run chart with statistically derived upper and lower control limits (ucl and lcl). The control chart demonstrates if a process is in statistical control. When properly designed, control charts provide an early warning of problems allowing for adjustments to be made before production of non-conforming products. We recommend microbial test results be plotted on control charts for individual measurements and fat test results be plotted on control charts featuring average and range of the fat test results (See Figure 2).

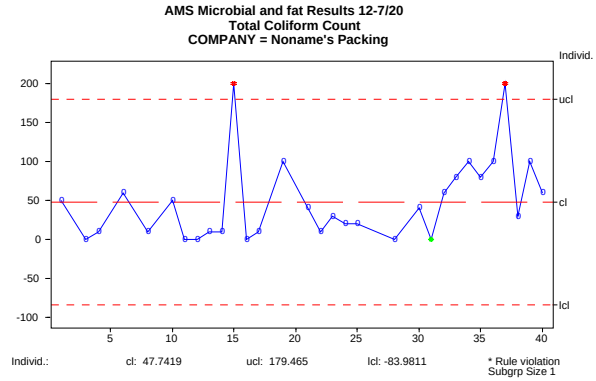


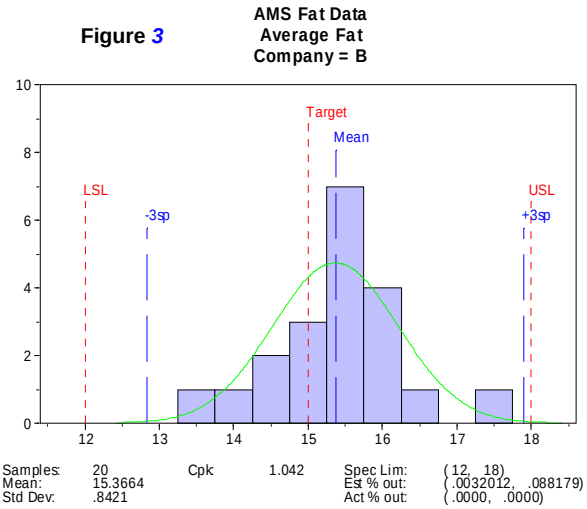
Figure *2*

Cpk – Process Capability Value (Cpk) is a capability analysis index used to determine if a process can meet specification limits. A Cpk value of 1 indicates that the process is producing at least 99.73% within the specification limit. Cpk values of 1 for many organizations have become the minimum requirement. However, the larger the Cpk values the better. Cpk differs from other process capability analyses since it considers the process average along with the distribution of test results. Since there is no lower specification limit for USDA microbial requirements, the calculation for Cpk will not involve relating the process average with a lower specification limit.

CPU - Process Capability Value (CPU) is the same as Cpk except that there is no lower specification limit. The process performance index is correctly known as a Centered Process Capability Upper Specification Limit only (CPU) (See Figure 3).

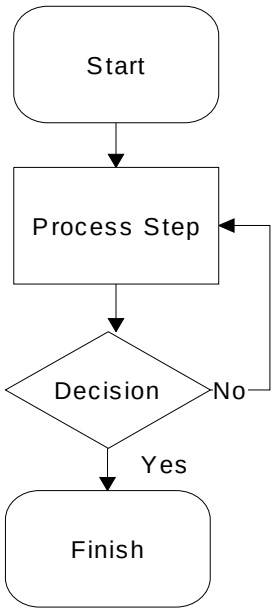
Excellent Condition - All product must be in excellent condition (e.g., exposed lean and fat surfaces shall be of a color and bloom normally associated with the class, grade, and cut of meat, and typical of meat which has been properly stored and handled). Cut surfaces and naturally exposed lean surfaces shall show no more than slight darkening or discoloration due to dehydration, aging, and/or microbial activity. The fat shall show no more than very slight discoloration due to oxidation or microbial activity. No odors foreign to fresh meat shall be present. Changes in color and odors characteristically associated with vacuum packaged meat in excellent condition shall be acceptable. Also, product shall show no evidence of mishandling. Beef must be maintained in excellent condition through processing, storage, and transit.

Figure *3*



Flow Charts – Flow charts depict all of the steps of a process. Standard symbols are used to identify the start, finish, processing steps and decision steps. It can be used to simplify a complex process so that it can be analyzed (Figure 4).

Figure *4*

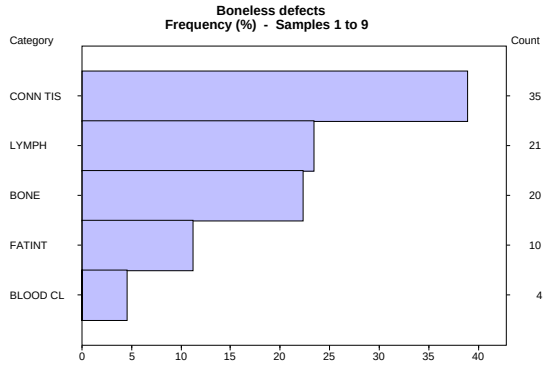


Histograms – The histogram shows a pictorial representation of the frequency of distribution of microbial test results over time. Sometimes referred to as process capability charts, histograms compare the distribution of the test results with AMS specification requirements. Use histograms along with control charts to better understand process capability (See Figure 3).

Pareto Diagrams – The Pareto diagram ranks the importance of different non-conformities. Typically, non-conformities are measured against frequency of occurrence. The Pareto analysis is helpful in identifying and justifying which problems will need to be solved first (see Figure 5).

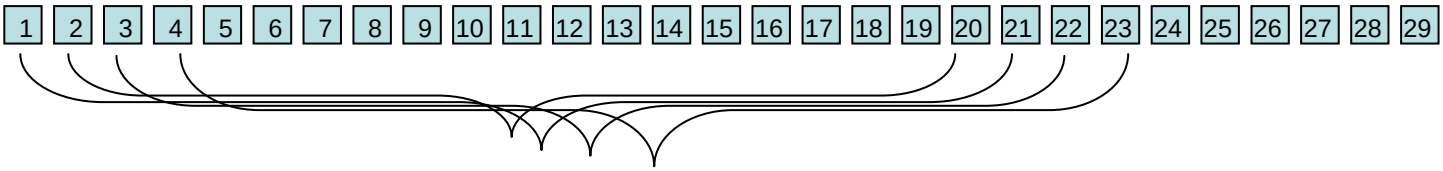
Process – For the purpose of this specification, a single process involves the input of a raw material on a production line with a value added activity resulting in a output that can is be further processed or meet a customer's need. A complex process involves output being another processes input. The production of ground beef is a complex process.

Figure 5



Process Capability Assessment on 20 consecutive lots – For the purpose of this specification, process capability assessments are conducted on data results from each lot for fat and microbial requirements. A process assessment involves sampling and testing of 20 consecutive lots (which always includes the last recorded result). Information from each lot will be evaluated with information from the preceding 19 lots (i.e., while in process assessment of the first 20 lots, the process was found to be capable, then assessment will continue on lot numbers 2-21).
This has often been referred to as a 'Rolling 20'. This assessment takes into account process variations that may be attributed to product, management, sources, and time (see Figure 6).

Figure 6



Random Sampling – A process of selecting a sample from a lot whereby each unit in the lot has an equal chance of being selected and is representative of the lot's production.

Statistical Process Control (SPC) – SPC is the primary analysis tool of quality improvement. The objective of any quality improvement strategy is to identify and reduce the amount of variation. SPC analyzes the variation in a process and is the applied science that assists suppliers to collect, organize and interpret microbial and fat test results on processing of ground beef destined for USDA.

SPC provides tools to help measure, identify, and eliminate variation from customer requirements (see Table 1).

Table 1

Tools for Statistical Process Control	
Flow Charts	Scatter Diagrams
Pareto Diagrams	Run Charts
Cause and Effect Diagrams	Control Charts
Histograms	Capability Assessment

Upper and lower control limits (ucl and lcl) – Control limits are statistical calculations of the distribution of test results. Upper and lower control limits represent +/- 3 standard deviations of the process results. Data plotted outside the limits represent special causes of variation. A process may be considered "out of statistical control" when results are outside these limits. Upper and lower control limits are not to be confused with specification limits. A supplier wishing to be an eligible participant in the Ground Beef Program shall have a process that is capable of producing within the specification limits (See figure 2).

Upper and lower specification limits (USL and LSL) – Normally, the customer sets the specification limits. The objective of the Ground Beef Purchase Program is to procure from ground beef processors that are statistically capable of meeting the upper specification limits specified within the TRS-GB. The specification limits reflect customer needs (See Figure 3).